REMARKS

Claims 58-97 are pending and stand rejected on various grounds. Claims 82, 83, 84, 86, 87, and 89 have been amended, and new claims 98-104 have been added. Claim 86 was amended to correct a typographical error ("aza" was substituted for "azav"). The amendments to the claims do not change their scope but only clarify features of the invention as originally claimed, and therefore the claims have an identical scope of equivalents to the original claims. Claim 104 is supported at e.g. page 22 lines 14-15 (hypercrosslinked adsorbent) and Table A (hypercrosslinked and non-hypercrosslinked adsorbent) beginning at page 24 of the specification. The amendments add no new matter.

Rejection of claims 82-84, 87 and 89 under 35 U.S.C. Sec. 112 second paragraph

Applicants thank the Examiner for the suggested language to clarify these claims, which language has been inserted into the claims.

Rejection of claims 58-73, 75-78, 81-85 and 87-97 under 35 U.S.C. Sec. 103(a)

Claims 58-73, 75-78, 81-85 and 87-97 stand rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over Foley et al. or Lee in view of Groeger et al. and Samejima. Specifically, the Office Action states that:

> " Foley et al. disclose adding a viral inactivating agent such as a psoralen compound for virus inactivation in a body fluid such as a blood product, and then removing the agent from the blood product with an adsorptive material (col. 4, line 42 to col, 5, line 61). The adsorptive material may be beads having a particulate size of 300-2000μm, an average pore diameter of 45-300 angstroms, and a surface area of 150 -1600 sq. meters/gram dry bead (col. 5, lines 18-20). The beads are enclosed in a container, cartridge or other means for housing the beads (col. 2 lines 30-33, and col. 4, lines 43-47) through which the blood product passes."

"Lee discloses using adsorbent beads to remove viral inactivating agents such as psoralens and psoralen degradation products from a blood product by passing the blood product through a cartilage containing the beads (col. 2, lines 23-37, and Figures 2 and 3). The beads can have a diameter of 0.1 to 2 mm (100-20 μm) (col. 2, line 31)."

"Groeger et al. discloses (col. 3, lines 11-22) a fibrous structure containing a composite fiber matrix loaded with adsorbent functional particles such as activated carbon beads (col. 5, line 50). the particles may have a size of 1 micron to 3-5 mm depending on the web structure (col. 6, lines 12-30). A preferred size for activated carbon particles is about 400 to 500 microns (col. 6, line 19). The fibrous structure has applications such as preparing high purity water, and for color or byproduct removal from whiskey and vinegar (col. 10, lines 25-27)."

"Samejima discloses a fiber matrix loaded with an adsorptive material such as activated carbon (col. 1 lines 11-39). Activated carbon has a surface area of 800-1800 m^2/gm (col. 1, line 29). The adsorptive material may have various uses including purification of tap water (col. 1, lines 35-36)."

"It would have been obvious to provide the adsorbent beads of Foley et al. or Lee within a matrix as taught by Groeger et al. and Samejima to obtain an expected advantage of the matrix holding the beads to facilitate handling of the beads and separation of the beads from a blood product. The container or cartridge of Foley et al. and Lee which contains the beads provides a housing for the beads. The adsorbent beads in the container or cartridge of Foley et al. and Lee are used to treat a blood product to produce a blood product for infusing into a patient (Foley et al. (col. 3, lines 5-15) and Lee (col. 3, lines 35-36). A blood product treated as disclosed by Foley et al. or Lee inherently has sufficient activity to be infused into a human as claimed. When using a matrix such as a fibrous matrix to hold the beads, it would have been obvious to use a matrix that results in a blood product suitable for infusion into a human since this is a objective of Foley et al. and Lee. Furthermore, the particle-containing matrix of Groeger et al. or Samejima can be used for purifying water or liquids to be consumed by a human, and such a matrix would appear to be capable of providing a blood product suitable for infusing into a human. The conditions of dependent claims would have been matters of obvious choice within the skill of the art in view of the disclosures of the references and knowledge common in the art."

Applicant respectfully traverses the rejection. To support a rejection under 35 U.S.C. Sec. 103(a), it is necessary to have some motivation such as a specific teaching that a particular combination of features found in separate references is desirable.

Applicant's claim 58 specifies a particular combination of features that define the claimed invention as a whole, and there is no motivation found in the references to select specific features from each reference and form the combination to provide the invention as a whole specified in claim 58.

The Office Action in particular states that "[i]t would have been obvious to provide the adsorbent beads of Foley et al. or Lee within a matrix as taught by Groeger et al. and Samejima to obtain an expected advantage of the matrix holding the beads to facilitate handling of the beads and separation of the beads from a blood product." Applicants submit that this observation does not consider the claimed invention as a whole. If the invention of claim 58 was merely to provide a convenient form of bead separation, there would be no need to specify a particle size range for the immobilized particles in addition to the immobilization. The invention of claim 58 as a whole provides a system in which adsorbent particles of a particular size and immobilized by a matrix provide the capability to remove a low molecular weight pathogen-inactivating compound and to produce in a flow process a biological product possessing one or more properties that are better than the property or properties of a similar biological material processed without immobilizing the particles, as taught by the specification.

Note especially that Groeger et al. and Samejima each indicate that particles outside the size range specified in claim 58 may be immobilized and used in their respective adsorptive fabrics. Samejima appears to be totally silent on size of adsorptive particles. Groeger et al. indicates that almost any size particle is suitable in his disclosure (anything from 1 micron in size to about 3 to 5 mm - col. 6 lines 12-14).

As the Examiner has noted, Groeger et al. expresses that 400 to 500 micron-sized activated carbon particles are preferred in Groeger et al.'s adsorbent (col. 6 lines 18-21).[1] But, Applicant notes that this particle size range is outside the particle-size range specified in Applicant's claims. Contrary to indicating that the claimed invention is obvious, Groeger et al.'s preference for a particular size of adsorbent material immobilized by fibers can indicate that Applicant's claimed invention *when considered in its entirety* is not obvious. Nothing in Groeger et al., alone or when combined with the other cited references, suggests the particular combination of features as specified in Applicant's claims.

Likewise, Lee and Foley et al. each indicate that particles outside the size range specified in claim 58 may be used in their respective systems. There is insufficient information in the references to suggest that adsorbent particles within the size range specified by Applicants should be selected and immobilized in a matrix and incorporated into a flow system for removing a pathogen inactivating compound from an aqueous biological composition. The references provide no reason to combine the attributes that lead to Applicants' invention of claim 58 when the invention as a whole is considered.

None of the references point to the desirability of combining all of the features specified in Applicants' claim 58. It is necessary to pick and choose features from the various references to find all of the features specified in Applicants' claim 58, but none of the references provide the guidance to make the selection.

Further, there is nothing in Foley et al. or Lee that suggests it would be desirable to immobilize adsorbent particles, regardless of their size, in a matrix. Neither Foley et al. nor Lee indicates that there is a problem with retaining adsorbent materials within their blood purification systems. For instance, Foley et al. states twice that no fines or charcoal were shed in their blood

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[1] Groeger et al.'s focus in making this statement is maintaining particles entrapped within a web of fibers, and the particle size of the adsorbent will vary depending on the size of fibers selected for the web. (Note that Groeger et al. in the patent at col. 6 lines 21-24 also mentions fusing smaller particles to fibers, but here again Groeger et al. expresses no preference for particular particle sizes.)

purification system (5:54-55, 6:15-16). Lee indicates that e.g. stainless steel screens effectively retain resin particles and prevent them from leaving the cartridge (2:25-27). The references fail to provide a reason for one of ordinary skill to modify the system of either of these references in the manner proposed in the Office Action. In addition, neither Groeger et al. nor Samejima provides the motivation to modify a blood purification system as disclosed in the Foley et al. and Lee patents, especially since both Groeger et al. and Samejima suggest uses for their respective products that are more germane to ingestion (filtering whisky, cider, and water for example) rather than infusion of the filtered product.

In view of the references being silent with respect to a motivation or reason to select specific features from all of the features disclosed in the various references and combine those specifically-selected features, Applicant submits that the invention of claim 58 and its dependent claims is not rendered unpatentable under 35 U.S.C. Sec. 103(a), and Applicant therefore requests reconsideration and withdrawal of the rejection.

With regard to claim 59, Applicants did not find a discussion of a sintered polymeric matrix in the cited references. Consequently, claim 59 is patentable over the cited references for the additional reason that the references, even when combined, do not teach all features of the claimed invention.

Rejection of claims 74, 79, 80, and 86

Claim 74 was rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85, and 87-97 and further in view of Davankov et al. Claims 79 and 80 were rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85, and 87-97 and further in view of Horowitz et al. (6,294,361). Claim 86 was rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85, and 87-97 and further in view of Wollowitz et al. (5,593,823).

Each of these claims depends from independent claim 58, and consequently each of these claims is patentable for the reasons discussed above.

In view of the above arguments, Applicants respectfully submit that the grounds for rejection under 35 U.S.C. Sec. 103 have been overcome and request that the rejections be withdrawn.

Rejection of claims for double patenting

Applicant notes the provisional nature of the rejection and are willing to submit a Terminal Disclaimer as an administrative convenience in the later-allowed application. Accordingly, Applicant requests deferral of this issue until such time as claims are allowed.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 282172000404.

Respectfully submitted,

Dated: April 11, 2003 By: _____

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